### REMARKS/ARGUMENTS

#### I. STATUS OF THE CLAIMS

With entry of this amendment, claims 7 and 8 are canceled. Claims 9 and 10 are currently amended. Claims 9-14 are pending. Support for the amendment to claims 9 and 10 can be found throughout the specification, in particular in formula (6) on page 22 of the specification and in the text on pages 23-24 of the specification. No new matter is added with this amendment.

### II. OBJECTION TO THE SPECIFICATION

The Examiner has objected to the use of the Trademark TAQMAN® on page 15 (ii) of the specification. See, page 2 item 4 of the Office Action. Applicants have amended the specification to correct the use of the Trademark as requested by the Examiner.

In view of the above, the Applicants respectfully request that the Examiner withdraw the objection.

# III. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH - CLARITY

Claim 9 is rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to point out and distinctly claim the subject matter the Applicants regard as the invention. Specifically, the Examiner alleges that the limitation in claim 9 that "the two quotients from step h)" in line 1 of step (i) of the claim is indefinite. The Examine alleges that the language is unclear because step h) upon which the limitation depends recites "calculating the quotients of the function values from step g) of the target nucleic acid and the reference nucleic acid for the sample to be analyzed as well as for the calibrator sample", which allegedly indicates calculating three quotients. Therefore, the Examiner alleges that "the two" is unclear and indefinite because it is not clear what "two quotients" represents out of the three calculated quotients.

Applicants respectfully traverse the rejection. Specifically, Applicants contend that the claim language as previously presented is not vague or indefinite because the ratio in

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step i) only involves the two quotients determined in step h). However, in an effort to expedite prosecution of the application, the Applicants have amended the claim to further clarify that only two quotients are determined in step h). A similar amendment has been made to claim 10, which also recites the same step.

Furthermore, to help the Examiner understand the steps of the method, the Applicants direct the Examiner's attention to step (f), where <u>four Cp-values</u> are determined, namely a target-Cp-value and a reference-Cp-value for the sample to be analyzed, *as well as* a target-Cp-value and a reference-Cp-value for the calibrator sample.

In step (g), the four values from step (f) are used to determine <u>four</u> corresponding function values using the respective functions from step (e).

In step (h) two quotients are formed from the four function values of step (g).

The <u>first quotient</u> being the "target function value/reference function value" for the sample and the <u>second quotient</u> being the "target function value"/"reference function value" for the calibrator sample.

Finally, in step (i) a ratio of the two quotients from step (h) is formed. The ratio formed in step (i) can be found as formula (6) on page 22 of the specification.

In view of the above, and claims 9 and 10 as presently recited, the Applicants respectfully request that the Examiner withdraw the rejection.

## IV. REJECTION UNDER 35 U.S.C. §103(a)

Claim 9 is rejected under 35 U.,S.C. §103(a) as allegedly unpatentable over Lowe et al. (WO 99/54510) in view Wittwer et al. (U.S. Pat. No 6,174,670).

Applicants respectfully traverse the rejection. Specifically, the Applicants contend that the rejection is improper because the Examiner has not established a proper *prima* facie case. In particular, claim 9 recites "a calibrator sample" in line 2 of step e). The Examiner has not indicated where Lowe et al., or Wittwer et al. teach or suggest the use of a calibrator sample to correct for the relative amount of a target nucleic acid to a reference nucleic acid as recited in claim 9. Because the Examiner has not indicated where the cited references teach all of the salient elements of the claim, a proper *prima facie* case has not been established and the

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rejection is improper. Moreover, Applicants submit that the references do not teach or suggest use of a calibrator sample as recited in the claims. In view of the above, the Applicants respectfully request that the Examiner withdraw the rejection.

### V. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 7-8 and 10-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 31-41 of co-pending application 09/823,712 (now U.S. Pat. No. 7,125,691 issued October 24, 2006).

Applicants respond by first noting that claims 7-8 are canceled, rendering the rejection to these claims moot. With regard to claims 10-14, applicants respectfully request that the Examiner hold the rejection in abeyance until the claims are indicated as otherwise allowable, at which time the applicants will file a terminal disclaimer if needed.

### **CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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